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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,905	10/07/2003	Stephen D. Pacetti	50623.243	6361
7590	07/08/2008		EXAMINER	
Cameron Kerrigan Squire, Sanders & Dempsey L.L.P. One Maritime Plaza, Suite 300 San Francisco, CA 94111			CAMERON, ERMA C	
			ART UNIT	PAPER NUMBER
			1792	
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			07/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/680,905	PACETTI ET AL.	
	Examiner	Art Unit	
	/Erma Cameron/	1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 May 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3,5-9,12-18,20-24,41,42 and 45-58 is/are pending in the application.
- 4a) Of the above claim(s) 9,14,41,54 and 58 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3,5-8,12,13,15-18,20-24,42,45-53 and 55-57 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/2/2008</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Response to Amendment

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, 5-9, 12-18, 20-24, 42, 45-57, drawn to coating with an applicator, classified in class 427, subclass 355+.
 - II. Claims 41 and 58, drawn to coating by submerging, classified in class 427, subclass 430.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Group I and II are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct processes. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include

(i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an

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election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. This application contains claims directed to the following patentably distinct species:

A)

- a) independent claims 1 and 18 (coating a medical device in general);
- b) independent claim 9 (coating the bore of a medical device);

B)

- c) leveling the composition using gas (claim 14);
- d) leveling the composition using a barrier (claim 15).

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including

any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

5. During a telephone conversation with James Reed on April 21, 2008 a provisional election was made WITH traverse to prosecute the invention of Group I and a) and d), claims 1-3, 5-8, 12-13, 15-18, 20-24, 42, 45-53 and 55-57. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9, 14, 41, 54 and 58 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. The rejection of Claims 42-44 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn because of the amendment filed 5/23/2008.

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8. Claims 1, 12, 18, 21, 23, 46, 47, 52, 53, 55 and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following is new matter that was not in the specification as filed:

Claim 1 “wherein the second direction is opposite to the first direction” ;
 “rotation about an axis that is not parallel to a rotation axis of the applicator”

Claim 12 250 rotations

Claim 18 (the specification does not mention a member rotating)

Claim 21

Claim 23

Claim 46

Claim 47

Claim 52

Claim 53

Claim 55

Claim 56

The applicant is requested to cancel all new matter.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-3, 5-8, 12-13, 15-18, 20-24, 42, 45-53, 55-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 1: it is not clear how the act of "rotating an applicator" causes a layer of coating composition to form on the applicator. There is no mention of the coating composition being contacted.

b) Claim 1: the meaning of "or refers to ...axis of the applicator" is unclear.

c) Claim 13: it appears that the wording should be "the rotating of the applicator step".

d) There is no antecedent basis for

claim 13 the applicator step

claim 13 the applicator substrate

claim 20 the outer surface

claim 42 the applicator substrate

claim 51 the roller

e) Claim 13, 15 and 22: the meaning of “substantially uniform” is unclear. How uniform does the layer have to be to be deemed “uniform”?

f) Claim 18: it is not clear how the act of "rotating a member" causes a layer of coating composition to form on the applicator. There is no mention of the coating composition being contacted.

g) Claim 18: the physical or spatial relationship between member and applicator and device is unclear.

h) Claim 47: it is not clear where the direction is being viewed from.

i) Claims 50 and 51: it is not clear when the submerging occurs.

j) Claim 57: it is not clear if the “members” of claim 57 are the same or different from the “member” of claim 18.

k) Claim 23: it is not clear if the member has the radius of curvature or if the applicator has the radius of curvature.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. The rejection of Claims 1, 5, 7-9, 16, 17, 41 and 43 under 35 U.S.C. 102(b) as being clearly anticipated by RD 434009, June 2000 is withdrawn because of the amendments filed 5/23/2008.

13. The rejection of Claims 1, 5, 7-9, 13, 14, 18, 20, 22-24 and 43-44 under 35 U.S.C. 102(b) as being clearly anticipated by Castro et al (6395326) is withdrawn because of the amendments filed 5/23/2008.

14. Claims 1, 5, 7-8, 13, 15-18, 20, 22-24, 47 and 49-51 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Shekalim et al (6971813).

‘813 teaches applying a polymer and drug coating to a roller from a reservoir or sponge and rotating the roller in one direction while the stent it contacts rotates in the other direction,

thus applying the coating to the stent. A wiper 18 may limit and level the coating on the roller. The application surface may be flat or curved (see Figure 1, 8:50-9:34, 10:38-13:48).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The rejection of Claims 2, 3, 6, 11-13 and 42 under 35 U.S.C. 103(a) as being unpatentable over RD 4343009 is withdrawn because of the amendments filed 5/23/2008.

17. The rejection of Claims 1-3, 5-8, 12-13, 16-18, 20-24, 42, 45-53 and 55-57 under 35 U.S.C. 103(a) as being unpatentable over Castro et al (6395326) is withdrawn because of the amendments filed 5/23/2008.

18. The rejection of Claim 15 under 35 U.S.C. 103(a) as being unpatentable over Castro et al (6395326) taken in view of Zarbatany et al (6610087) is withdrawn because of the amendment filed 5/23/2008.

19. Claims 2-3, 6, 12, 21, 42, 46, 48, 52-53 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shekalim et al (6971813).

‘813 is applied here for the reasons given above.

‘813 does not teach the viscosity of the coating composition, the rate of revolution of the stent and roller, grooves on the roller or the thickness of the coating on the roller, but it would have been obvious to one of ordinary skill in the art to have optimized these parameters through no more than routine experimentation as they are known to be parameters that will affect the coating quality.

20. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shekalim et al (6971813) taken in view of Pinchuk et al (5968091).

‘813 is applied here for the reasons given above.

‘813 teaches that the stent rotates while coating material is applied to it (10:54-60), but does not teach how the rotation occurs.

‘091 teaches that a mandrel may be used to rotate a stent while it is being coated (Example 9).

It would have been obvious to one of ordinary skill in the art to have used the mandrel of '091 in the '813 coating process to rotate the stent, because of the teaching of '091 that a mandrel is a conventional method of rotating a stent.

Conclusion

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Erma Cameron/ whose telephone number is 571-272-1416. The examiner can normally be reached on 8:30-6:00, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Erma Cameron/

Primary Examiner

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July 7, 2008